



BOARD OF EQUALIZATION

BUSINESS TAXES COMMITTEE MEETING MINUTES

HONORABLE DEAN F. ANDAL, COMMITTEE CHAIR

450 N STREET, SACRAMENTO

MEETING DATE: AUGUST 31, 1999, TIME: 10:00 A.M.

ACTION ITEMS & STATUS REPORT ITEMS

Agenda Item No: 1

Title: Proposed Regulatory Changes to Reflect Changes in the Motor Vehicle Fuel License Tax Law (Regulation 1132)

Issue/Topic:

Should the Board authorize the publication of amendments to Motor Vehicle Fuel License Tax Regulation 1132, *Shipments Out of the State*, to conform the regulation to amended sections of the Motor Vehicle Fuel License Tax Law and make other necessary changes?

Committee Discussion:

Discussion of the agenda was as follows.

Action 1, Consent

Staff and industry agreed on the proposed language of the regulations. There was no discussion of these items.

Action 2, Authorization to Publish

There was no discussion of this item.

Committee Action/Recommendation/Direction:

Action 1, Consent

The committee approved all consent items.

Action 2, Authorization to Publish

The committee directed staff to request authority to publish the attached revised Motor Vehicle Fuel License Tax Regulation 1132, *Shipments Out of the State*.

Agenda Item No: 2

Title: Proposed Regulatory Changes to Clarify Application of Tax to Medicines (Regulation 1591)

Issue/Topic:

Should Regulation 1591 be amended to reorganize the current version, incorporate industry's proposed amendments, and rewrite various sections to clarify the application of tax on the sales of medicines and related items?

Committee Discussion:

Staff explained that, in cooperation with industry representatives, Regulation 1591, *Medicines and Medical Supplies, Devices and Appliances*, was reorganized into five separate proposed regulations, with industry's proposed language and suggestions included when appropriate. In addition, staff recommends that the reorganization include: 1) information from various annotated legal opinions; 2) clarification that the sale or use of replacement parts for kidney dialysis machines is exempt; 3) clarification that "physician" also includes a podiatrist for the purposes of section 6369.2; and 4) clarification that the use of sample clinical trial drugs is not subject to tax when such samples qualify as medicines, including patches impregnated with medicines. However, staff does not agree with industry that statutory authority exists to amend the regulation to exempt the sale or use of diabetic patient aids.

Discussion of the agenda was as follows:

Action 1, Consent

Proposed language was agreed upon by staff and industry. There was no discussion of these items.

Action 2, Application of Tax to Diabetic Patient Aids (Glucose Test Strips and Lancets)

Staff and industry were not in agreement concerning language proposed by industry for amended Regulation 1591 (e)(7), "Diagnostic Substances, Test Kits, and Equipment," and proposed Regulation 1591.1(b)(4), *Insulin and Insulin Syringes*. Staff stated its view that the legislature has not specifically designated glucose test strips and lancets as exempt from tax, and they do not qualify as a "medicine." These items are for *inter vivos* (outside the body) use, and the Board has historically treated items used outside the body as not qualified for exemption as a medicine. The committee was addressed by Mr. Carlo Michelotti, representing the California Pharmacists Association. Mr. Michelotti explained the use of the glucose test strips and lancets, stating that the lancet comes into intimate contact with the body and the test strips are essential to the day-to-day treatment of diabetes. He stated his view that both items are part of the same process that is addressed in the exemption for insulin and insulin syringes (Revenue and Taxation Code 6369(e)).

Committee Action/Recommendation/Direction:Action 1, Consent

The committee approved all consent items.

Action 2, Application of Tax to Diabetic Patient Aids (Glucose Test Strips and Lancets)

The committee approved the adoption of industry's proposal.

Action 3, Authorization to Publish

The committee directed staff to request authority to publish the following revised and proposed regulations, copies of which are attached:

Regulation 1591, *Medicines and Medical Devices* (amended)

Regulation 1591.1, *Medical Devices, Appliances and Supplies* (proposed)

Regulation 1591.2, *Wheelchairs, Crutches, Canes, and Walkers* (proposed)

Regulation 1591.3, *Vehicles for Physically Handicapped Persons* (proposed)

Regulation 1591.4, *Medical Oxygen Delivery Systems* (proposed)

Approved: /s/ Dean F. Andar
Honorable Dean F. Andar, Committee Chair

/s/ E. L. Sorensen, Jr.
E. L. Sorensen, Jr., Executive Director

BOARD APPROVED

at the 9/1/99 Board Meeting

/s/ Janice Masterton
Janice Masterton, Chief
Board Proceedings Division

Regulation 1132. SHIPMENTS OUT OF THE STATE.**(a) DEFINITIONS.**

(1) EXPORT. An export of motor vehicle fuel is the delivery or shipment of fuel by the distributor from a point in this state to a point outside of ~~the~~ this state. The fuel is not exported if it is diverted in transit or for any reason is not actually delivered out of this state, regardless of documentary evidence held by the distributor respecting delivery of the fuel to a carrier for out-of-state shipment or to a vessel clearing for an out-of-state port, when pursuant to the contract of sale the fuel is delivered by the distributor to:

~~(A) the out-of-state point by facilities operated by the distributor,~~

~~(B) a carrier for shipment to a consignee at the out-of-state point,~~

~~(C) a customs broker or forwarding agent for shipment to a location outside of the state, or~~

~~(D) a vessel clearing from a port of this state for a port outside of this state.~~

~~The fuel is not exported if it is diverted in transit or for any reason is not actually delivered out of the state, regardless of documentary evidence held by the distributor respecting delivery of the fuel to a carrier for out-of-state shipment or to a vessel clearing for an out-of-state port.~~

(2) CARRIER. A carrier means a person or firm who is regularly engaged in the business of transporting for compensation property owned by other persons and includes both common and contract carriers. The carrier may be hired by either the purchaser or the distributor.

(b) REQUIREMENTS. A distributor may not claim an export exemption from motor vehicle fuel license tax under Revenue and Taxation Code Section 7401(a)(2) unless the motor vehicle fuel is in fact exported and the export is accomplished in the manner specified in either (1) or (2) below:

(1) The distributor claiming the exemption from tax shows that it delivered the motor vehicle fuel to any vessel clearing from a port of this state for a port outside of this state and the fuel was actually exported from this state in the vessel; or

(2) The distributor claiming the exemption from tax shows that it exported the motor vehicle fuel from this state pursuant to a written contract requiring delivery by the distributor of the fuel to:

(A) the out-of-state point by facilities operated by the distributor,

(B) a carrier for shipment to a consignee at the out-of-state point, or

(C) a customs broker or forwarding agent for shipment to a location outside of this state.

~~(b)~~ **EXPORTS OF EX-TAX FUEL.** The tax does not apply to the distribution of ex-tax motor vehicle fuel actually exported. Stock transfers of ex-tax fuel to a point outside the state are not distributions and are not subject to the tax.

A distributor must claim the exemption for the export of ex-tax fuel on the return filed for the period in which the export was made. If a distributor fails to claim the exemption on the return and ~~If the~~ tax is erroneously paid on the ex-tax exports of fuel, a timely claim for refund must be filed with the Board pursuant to Section 8128 ~~Chapter 7, Article 2~~ of the Motor Vehicle Fuel License Tax Law in order to obtain ~~credit or~~ a refund of the amount of taxes so overpaid.

~~(e)~~ **EXPORTS OF TAX-PAID FUEL.** In lieu of claiming a refund of tax for exports of tax-paid fuel with the State Controller as provided by Section 8101(b) of the Revenue and Taxation Code, a distributor may take a credit on its return for tax-paid fuel when the fuel is exported to a point outside the state or when stock is transferred to a point outside the state. The credit must be claimed on a return filed within ~~the later of~~ three months after the close of the calendar month in which the tax-paid fuel is exported ~~or 13 months from the date of purchase of the fuel~~. If the credit exceeds the taxable distributions of motor vehicle fuel for the period in which the credit may be taken, refund of the tax on the excess gallonage can only be obtained by filing a claim for refund with the State Controller.

Failure to take credit on a return filed within ~~the later of~~ three months after the close of the calendar month in which the tax-paid fuel is exported ~~or 13 months from the date of purchase of the fuel~~ does not give rise to a right to a file a claim for refund with the Board pursuant to Section 8126 of the Revenue and Taxation Code. Instead, claims for refund for tax-paid fuel exported must be filed with the State Controller within three years from the date of purchase of the fuel.

~~(d)~~ **DOCUMENTATION REQUIRED FOR SUPPORT.** All shipments of motor vehicle fuel to points outside of the state for which tax exemption or credit is claimed on a tax return shall be reported on a schedule accompanying the return for the period for which the exemption or credit is claimed. ~~supported by export certificates made by persons having actual knowledge of the fact that the fuel has been shipped out the state. These certificates shall be completed in quadruplicate on forms furnished by the Board. Within three months after the close of the calendar month in which the shipments are made, the original and two copies of the certificates shall be filed with the Board. The remaining copy shall be retained for audit purposes.~~

The distributor must retain documentation to support ~~the intent to deliver fuel out of state and the~~ delivery of the fuel by the distributor at an out-of-state location for all exemptions or credits. Documentation may include, but is not limited to, contracts, bills of lading, delivery tickets, or meter readings. The distributor has the burden of providing the proper substantiation and documentation to support the exemption or credit.

Authority: Section 8251 Revenue and Taxation Code

Reference: Sections 7401, ~~7402, 7403, 7404~~, 7651, 8101, 8102, 8105, 8106.5, 8126, 8128, 8129, 8301 and 8305 Revenue and Taxation Code.

REGULATION 1591. MEDICINES AND MEDICAL Supplies, DEVICES and Appliances

Reference: Sections 6006 and 6369, ~~6369.1, 6369.2, 6369.4 and 6369.5~~ Revenue and Taxation Code.

~~(a) General. Tax applies to retail sales of drugs, medicines, and other tangible personal property by pharmacists and others except as follows:~~

~~Tax does not apply to sales of medicines for the treatment of a human being which medicines are:~~

~~—(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a registered pharmacist in accordance with law, or~~

~~—(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or~~

~~—(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or~~

~~—(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or~~

~~—(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or~~

~~—(6) hemodialysis products supplied on order of a licensed physician to a patient by a registered pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4054 or 4059 of the Business and Professions Code to distribute such products directly to a hemodialysis patient, or~~

~~—(7) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (a)(7) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.~~

(a) Definitions.

(1) Administer. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) Dispense. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) Furnish. “Furnish” means to supply by any means, by sale or otherwise.

(4) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:

“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer....”

(5) Pharmacist. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of Section 4200 of the Business & Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.”

(6) Pharmacy. “Pharmacy” means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of Section 4037 of the Business and Professions Code.

(7) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(8) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California

and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(9) Medicines. “Medicines” means any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) Definition of “Medicines.” Medicines. The term “medicines” includes the following items:

(1) ~~any~~ Preparations and Similar Substances. Preparations and similar substances or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which ~~is~~are commonly recognized as a substance or preparation intended for such use; qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

“Preparations” and similar “substances” include, but are not limited to, drugs such as penicillin, and other antibiotics, “dangerous drugs” (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines.

(2) Permanently Implanted Articles. ~~Bone screws, bone pins, pacemakers, and other A~~articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. ~~The term also includes sutures, whether or not permanently implanted. A nonreturnable, nonreusable needle fused or prethreaded to a suture is regarded as a part of the suture.~~An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not be limited to, permanently implanted artificial sphincters; bone screws and bone pins; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheter; temporary myocardial pacing leads used during surgery

and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.

(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) Orthotic Devices. Orthotic devices; ~~and or~~ their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure; ~~provided, that orthopedic shoes and supportive devices for the foot are not exempt unless they are an integral part of a leg brace or artificial leg or are custom made biomechanical foot orthoses.~~ are medicines as provided under Section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

~~“Custom made biomechanical foot orthosis” means a device which is made on a positive model of the individual patient’s foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology. The device described above excludes~~

- ~~—(A) any pre made or pre molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;~~
- ~~—(B) any foot orthosis fabricated directly on the patient’s foot regardless of the method and materials used and regardless of its individual character; and~~
- ~~—(C) any foot orthosis fabricated inside of the patient’s shoe regardless of the method of manufacture and materials used and regardless of its individual character.~~

“Orthotic devices” worn on the body of the person includes, but are ~~is~~ not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device will not qualify as a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device that is made on a positive model of the individual patient’s foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

A “custom-made biomechanical foot orthosis” does not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient’s foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient’s shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) Prosthetic Devices. Prosthetic devices ~~or~~ and their replacements parts; designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body ~~other than auditory, ophthalmic and ocular devices or appliances, and other than dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth and other dental prosthetic materials and devices.~~ are medicines as provided under Section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such person, shall be deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) ~~Artificial eyes, or their replacement parts, intraocular lenses for human beings, and ear implants.~~

(76) Drug Infusion Devices. Programmable drug infusion devices worn on or implanted in the human body that automatically cause the infusion of measured quantities of medicine on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) Exclusions from ~~Term~~ the Definition of “Medicines.”

Except as otherwise provided in ~~(b)(2) through (b)(7) above,~~ subdivision (b), the following items are specifically excluded from the term definition of medicines:. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(6)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).

~~(d) Who is a “Registered Pharmacist”. A “registered pharmacist” is defined under Section 4036 of the Business and Professions Code as follows:~~

~~“‘Pharmacist’ means a person to whom a license has been issued by the board, under the provisions of Section 4200, except as specifically provided otherwise in this chapter.”~~

(d) Application of Tax – In General

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a ~~registered~~ pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision (d)(6) applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

~~(e) What Constitutes a "Prescription." Section 4040 of the Business and Professions Code defines "prescription" as follows:~~

~~"'Prescription' means an oral, written, or electronic transmission order that is both of the following: (1) Given individually for the person or persons for whom ordered that includes all of the following: (A) The name or names and address of the patient or patients. (B) The name and quantity of the drug or device prescribed and the directions for use. (C) The date of issue. (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed. (E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients. (F) If in writing, signed by the prescriber issuing the order. (2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian licensed in this state."~~

~~No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being.~~

(e) Specific Tax Applications

(1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) Licensed Physician, Dentist, or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the

treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) *Health Facility.* Tax does not apply to sales of medicines by a health facility (as defined) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax also does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) *Pharmaceutical Manufacturer or Distributor.* Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration’s drug development and approval process. “Clinical trial medicines” are substances or preparations approved as Investigational New Drugs by the United States Food and Drug Administration intended for treatment of, and application to, the human body, and which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision (e)(4). Thus, the use of placebos is subject to tax.

(5) *Antimicrobial Agents Used by Hospital Personnel.* Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient’s treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and, as such, the sale or use of these products is subject to tax.

(6) *Vitamins, Minerals, Herbs, and Other Such Supplements.* In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(7) *Diagnostic Substances, Test Kits, and Equipment.* Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment, they are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines for the purposes of the exemption provided under Section 6369.

Except as otherwise provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether or not they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

~~(f) *Licensed Physician, Dentist or Podiatrist.* Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge therefor to patients.~~

~~(g) *Health Facility.* “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:~~

~~———“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24 hour stay or longer,...”~~

~~Tax does not apply to sales by a health facility of medicines for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales to a health facility of medicines for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.~~

~~(h) *Insulin.* “Insulin” and “insulin syringes” furnished by a registered pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369.~~

~~(i) Orthotic and Prosthetic Devices. Orthotic and prosthetic devices, and replacement parts for these devices, furnished pursuant to the written order of a licensed physician or podiatrist, shall be deemed to be dispensed on prescription within the meaning of paragraph (a)(1), whether or not the devices are furnished by a registered pharmacist.~~

~~(j) Mammary Prostheses and Ostomy Appliances and Supplies. Mammary prostheses, and any appliances and related supplies necessary as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste, shall be deemed to be dispensed on prescription within the meaning of Section 6369. Qualifying mammary prostheses and ostomy appliances and supplies include, but are not limited to, bras to hold a mammary prosthesis in place, filler pads, lymphedema arm sleeves, adhesive spray and remover, belts, catheters used as a result of an artificial opening created in the human body, colostomy bags, deodorant used on the person of the user, karaya rings, antacid used externally as a skin ointment, skin gel, nonallergic paper tape and gauze, skin bond cement, tincture of benzoin applied topically as a protective, urinary drainage appliances, closed stoma bags, drainable stoma bags, loop ostomy supplies, and tubing.~~

~~The term “appliances” and “related supplies” includes kidney dialysis machines, and the tubing, pumps, blood sets, fistula sets, and shunts used in conjunction with such machines.~~

~~(k) Wheelchairs, Crutches, Canes, Quad Canes and Walkers. Tax does not apply to sales, including leases that are “sales,” of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, and walkers and replacement parts for these devices when sold to an individual for the personal use of that individual as directed by a licensed physician.~~

~~(l) Modifications to Vehicles used by Physically Handicapped Persons. Tax does not apply to the sale of items and materials used to modify a vehicle for physically handicapped persons which are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. The exemption does not extend to tools and supplies used in modifying the vehicle and not incorporated into, attached to, or installed on the vehicle.~~

~~In the case of a sale of a modified vehicle to a physically handicapped person, tax does not apply to the gross receipts attributable to that portion of the vehicle which has been modified to enable the vehicle to be used to transport a physically handicapped person or persons.~~

~~—(1) The term, “physically handicapped” persons, as used in this section, includes disabled persons described in Vehicle Code Section 5007 as qualified for special parking privileges.~~

~~—(2) The term, “vehicle,” as used in this section, includes all devices which qualify under Vehicle Code Section 670 as “vehicles” including but not limited to automobiles, vans, trucks, mobilehomes and trailercoaches.~~

~~—(3) “Vehicles” qualifying under this section mean and include:~~

~~—(A) Vehicles which are owned and operated by physically handicapped persons.~~

~~—(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 5007 if the vehicle were registered to the physically handicapped person or persons.~~

~~(m) Medical Oxygen Delivery Systems. Tax does not apply to the sale of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. “Medical oxygen delivery systems” includes liquid oxygen containers, high pressure cylinders, regulators, oxygen concentrators, tubes, masks and related items necessary for the delivery of oxygen to the person. The term also includes repair and replacement parts for use in such a system.~~

~~(n) Balloon Catheters. Sales of intra-aortic balloon pump catheters and coronary angioplasty balloon catheters are not subject to tax. Sales of related supplies are subject to tax. The term “related supplies” includes, but is not limited to, coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, hemostatic valves, inflation devices, and syringes.~~

~~(of)~~ Medical Insurance Payments

(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) Medicare

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the U.S. Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the U.S. Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the U.S. Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as an exempt sale of a medicine), the sale is subject to tax.

~~(p3)~~ Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(gg) Records.

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to Section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Section 6369:

- Name of purchaser
- Name of doctor
- Date of sale
- Item sold
- The sale price

(2) “Double Deduction” Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

History: Effective January 1, 1962.

Amended May 16, 1962.

Amended September 18, 1963, effective as amended September 20, 1963.

Amended and renumbered December 10, 1969, effective January 11, 1970.

Amended May 4, 1971, effective July 1, 1971.

Amended September 14, 1972, effective September 15, 1972.

Amended January 18, 1973, effective January 26, 1973.

Amended October 20, 1977, effective October 28, 1977. Changed to conform to Revenue and Taxation Code Section 6369 and 6369.2. Added orthotic and prosthetic devices to definition of “medicines;” excluded “dentures” from the definition of “medicines;” added mammary prostheses and ostomy appliances to items to be dispensed on prescription; added wheelchairs, crutches, canes, quad canes and walkers as exempt items. Changed all references to the term “hospital” to “health facility” as defined in Section 1250 of the Health and Safety Code.

Amended March 1, 1978, effective April 29, 1978. In (b)(4) added list of specific orthotic devices; in (b)(5) added list of prosthetic devices; in (c)(1), (2) and (3) included specific items excluded from the term “medicines”; in (g) made

grammatical change; in (i) added list of specific items to be included under this section; in (j) added leases to transactions to which tax does not apply and provided that tax applies to all replacement parts; in (m) deleted references to former Section 280 of Title 17, California Administrative Code, and added (1) specifying acceptable documentation for exempt sales and (3) suggesting use of Regulation 1667 "Exemption Certificates."

Amended July 27, 1978, effective July 31, 1978. In (b)(5) deleted dental crowns, caps and inlays from definition of "medicines"; in (c)(1) added crowns, caps, inlays and other dental prosthetic materials and devices to exclusions from term "medicines"; in (c)(2) added orthodontic appliances to exclusions from term "medicines"; in (i) provided that orthotic and prosthetic devices shall be deemed to be dispensed on prescription; in (k) exempted replacement parts for wheelchairs, crutches, canes, quad canes and walkers from tax.

Amended September 27, 1978, effective November 18, 1978. In (b)(5) added intraocular lenses and ear implants; moved general exclusionary language from (c)(3) to (c); to (c)(2) added reference to footnote 3; and added reference to orthodontic appliances and devices to footnote 3.

Amended September 26, 1979, effective November 16, 1979. Adds (1); reletters former (1) and following subsection.

Amended July 27, 1983, effective November 17, 1983. Added subdivision (b)(7); changed reference in first sentence of (c) from (b)(6) to (b)(7). Added "and, on or after January 1, 1983, "insulin syringes" to subdivision (h) and added subdivision (m); relettered former subdivisions (m), (n), (o) to (n), (o), (p).

Amended August 24, 1988, effective October 7, 1989. In subdivision (b)(4) added provisions to include "custom made biomechanical foot orthoses" within the definition of the term medicines.

Amended October 26, 1993, effective February 17, 1994. Amended subdivision (k) to provide the exemption from tax for white canes used by the legally blind; removed obsolete dates in subdivisions (b)(4), (b)(7), (h), and (m).

Amended June 27, 1996, effective August 23, 1996. Amended subdivisions (b)(4) and (5) to correct spelling errors; added new subdivision (n), and renumbered former subdivisions (n), (o), and (p) as (o), (p), and (q), respectively.

Amended November 19, 1996, effective December 19, 1996. Added new (a)(7) to incorporate provisions of Assembly Bill 3836 (Chapter 857, Statutes of 1994).

Amended August 10, 1998, effective October 17, 1998. Amended subdivisions (a)(6), (d), (e) to reflect changes in sections of the Business and Professions Code; corrected spelling errors in subdivisions (b)(4)(A) and (b)(5); changed "which" to "that" in subdivision (g); removed obsolete date in subdivision (k); amended subdivisions (l)(1) and (l)(3)(B) to reflect changes in sections of the California Vehicle Code.

REGULATION 1591.1. SPECIFIC MEDICAL DEVICES, APPLIANCES, AND RELATED SUPPLIES

(a) Definitions.

(1) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(2) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(b) Specific Applications.

(1) Hemodialysis Products. Tax does not apply to the sale or use of hemodialysis products supplied on order of a licensed physician and surgeon to a patient by a pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4054 or 4059 of the Business and Professions Code to distribute such products directly to the patient.

(2) Mammary Prostheses and Ostomy Appliances and Related Supplies. Tax does not apply to the sale or use of mammary prostheses and ostomy appliances and related supplies required as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste when sold or furnished under one of the conditions provided in Regulation 1591 subdivision (d)(1) through (d)(6). The mammary prostheses devices and ostomy appliances and related supplies do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription as long as they are furnished pursuant to a written order of a person authorized to prescribe.

Ostomy appliances and related supplies must be used in postoperative situations or sold as an accommodation to patients following surgery in order to qualify as medicines. When used as an adjunct to surgical procedures, the sale or use of these items is subject to tax unless the appliances remain in the patient for postoperative purposes.

Qualifying mammary prostheses and qualifying ostomy appliances and related supplies include, but are not limited to, bras to hold a mammary prosthesis in place, filler pads, lymphedema arm sleeves, adhesive spray and remover; catheters used as a result of an artificial opening created in the human body; colostomy bags; deodorant used on the person of the user; karaya rings; antacid used externally as a skin ointment; skin gel; nonallergic paper tape and gauze; skin bond cement; tincture of benzoin applied topically as a protective; urinary drainage appliances; closed stoma bags; drainable stoma bags; loop ostomy supplies and tubing; and endotracheal and tracheotomy tubes used for the evacuation of metabolic waste when used post-operatively or for home care. Tracheostomy tubes used to facilitate the passage of air do not qualify as medicines for the purposes of Section 6369.

Kidney Dialysis Machines. The term “ostomy appliances” and “related supplies” includes kidney dialysis machines, replacement parts for the kidney dialysis machines, and the catheters, dialysis fluid additives, volumetric infusion pumps, tubing, blood sets, fistula sets, and shunts used in conjunction with such machines. In order to qualify as a “related supply,” an item must be a necessary and integral part of the machine itself, or a substance or preparation intended for external or internal application to the human body of the patient undergoing dialysis.

(3) Catheters. Generally, sales of catheters are subject to tax in the same manner as other sales of tangible personal property. However, sales of the following types of catheters are not subject to tax.

(A) Intra-aortic balloon pump catheters and coronary angioplasty balloon catheters.

However, sales of related supplies are subject to tax. The term “related supplies” includes, but is not limited to, coronary guiding catheters, coronary guide wires, guide wire introducers, sheath introducer systems, torquing devices, hemostatic valves, inflation devices, and syringes.

(B) Catheters which are permanently implanted in the human body and assist the functioning of a natural organ, artery, vein, or limb and remain or dissolve in the body.

(C) Catheters used for drainage purposes through which an artificial opening is created in the human body. Such catheters qualify as ostomy materials and related supplies.

(D) Catheters or similar types of devices used for drainage purposes through natural openings in the human body to assist or replace the functioning of a natural part of the human body. Such catheters are designed to be worn on or in the body of the user and qualify as prosthetic devices.

(4) Insulin and Insulin Syringes. “Insulin” and “insulin syringes” furnished by a pharmacist to a person for treatment of diabetes as directed by a physician shall be deemed to be dispensed on prescription within the meaning of Section 6369(e). As such, the sale or use of insulin and insulin syringes furnished by a pharmacist to a person for treatment of diabetes, as directed by a physician, is exempt from tax.

Glucose test strips and skin puncture lancets furnished by a registered pharmacist that are used by a diabetic patient to determine his or her own blood sugar level and the necessity for and amount of insulin and/or other diabetic control medication needed to treat the disease in accordance with a physician’s instructions are an integral and necessary active part of the use of insulin and insulin syringes or other anti-diabetic medications and, accordingly, are not subject to sale or use

tax pursuant to subsection (e) of Section 6369. These medical supplies are not medicines and their sale or use does not qualify for tax exemption under subsections (a) or (b) of Section 6369.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.1, Revenue and Taxation Code.

REGULATION 1591.2. WHEELCHAIRS, CRUTCHES, CANES, AND WALKERS.

(a) Definitions.

(1) Physician. For purposes of this regulation, “physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. Physician, as defined, includes doctors of medicines (MD), doctors of osteopathy (DO), and doctors of podiatric medicine (DPM).

(2) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(3) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code, which provides that:

“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer....”

(b) Tax Application. Tax does not apply to the sale or use, including leases that are continuing sales and purchases, of wheelchairs; crutches; canes; quad canes; white canes used by the legally blind; walkers; and replacement parts for these devices when sold to an individual for the personal use of that individual as directed by a licensed physician. Electric three-wheel scooters that are similar in both design and function to a conventional electric wheelchair, qualify as a wheelchair for the purposes of Section 6369.2. When the scooters are sold or leased to an individual for the personal use of that individual as directed by a licensed physician their sale or use qualifies for an exemption from tax.

“Replacement parts” include, but are not limited to, batteries for electric wheelchairs; belts and cushions sold to replace or supplement the basic items originally sold with wheelchairs, lap boards and trays attached to wheelchairs and considered a part of the wheelchair; and rubber tips, wheels, and other such items prescribed for an individual to replace an original component of the device sold. “Replacement parts” do not include items such as mechanical devices that aid the patient in eating or writing unless the items are part of the device itself, or restraints or other such items sold to an individual, but which do not become a part of the wheelchair or other such prescribed device.

(c) Sales to Health Facilities. Sales, or leases that are continuing sales and purchases, of wheelchairs, crutches, canes, and walkers to hospitals or other health facilities for use by patients while at the facilities are subject to tax. Such sales or leases are not considered sold to an individual for the individual's personal use as directed by a physician. However, when wheelchairs, crutches, canes, and walkers are ordered by a hospital or health facility on behalf of a specific patient, as directed by a physician, the items may be considered to be purchased by an individual for his or her own personal use as required under Section 6369.2 and, therefore, the sale will qualify for exemption from tax.

(d) Sales to Insured Persons. The exemption for qualifying retail sales of wheelchairs, crutches, canes, quad canes, white canes used by the legally blind, walkers, and replacement parts for these devices is not affected by the fact that charges to the individual to whom such items are sold, may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.2, Revenue and Taxation Code.

REGULATION 1591.3. VEHICLES FOR PHYSICALLY HANDICAPPED PERSONS.

(a) Definitions.

(1) Physically Handicapped Persons. For purposes of this regulation, “physically handicapped” persons include disabled persons described in Vehicle Code Section 5007 as qualified for special parking privileges.

(2) Vehicle. For purposes of this regulation, “vehicle” includes all devices that qualify under Vehicle Code Section 670 as “vehicles” including, but not limited to, automobiles, vans, trucks, mobilehomes and trailercoaches. “Vehicles” qualifying under this regulation mean and include:

(A) Vehicles which are owned and operated by physically handicapped persons and,

(B) Vehicles which are used in the public or private transport of physically handicapped persons and which would otherwise qualify for a distinguishing license plate pursuant to Vehicle Code Section 5007 if the vehicle were registered to the physically handicapped person or persons.

(b) Application of Tax. Tax does not apply to the sale or use of items and materials used to modify a vehicle for physically handicapped persons when such items are necessary to enable the vehicle to be used to transport a physically handicapped person or persons. Tax does not apply whether the property is installed by the retailer or is sold for installation by other persons. However, sales or purchases of tools and supplies used in modifying the vehicle and which are not incorporated into, attached to, or installed on the vehicle are subject to tax.

Items and materials considered necessary to enable a vehicle to be used to transport a physically handicapped person include, but are not limited to, an interlock system; upper torso restraint; an airbag of a unique type to raise or lower the vehicle for loading or unloading; running boards on lower side of vehicle; a bolt cam used to restrain a wheelchair inside a van; seat belts; a tire carrier to hold a spare and which is installed within reach of a handicapped person; AC lights to illuminate the ramp or elevator area; hardware for privacy curtains; air compressor for use with medical equipment; a 12-volt receptacle to supply power to medical equipment; a 4-point tie down system to restrain a wheelchair; and an allocable portion(s) of the various interior packages, interior materials, and conversions necessary to modify the vehicle for transport of physically handicapped persons.

Items and materials that are generally not considered necessary to enable a vehicle to be used to transport a physically handicapped person include, but are not limited to, an upper torso durable pad (unless part of the restraint); portable ramps (telescopic); air conditioners (unless necessary for the transport of certain types of disabled persons); a fire extinguisher; a CB radio (unless shown to be necessary to the transport of certain types of disabled persons); leather seat covers; extra windows and their accessories; upgrades to the interior (upgrade to leather seats); and an engine cover. The sale or use of such items, whether installed on a vehicle to be used for transport of physically handicapped persons or not, are generally subject to tax.

(c) Sales of Modified Vehicles. Tax does not apply to the gross receipts attributable to the portion of a vehicle that has been modified to enable the vehicle to be used to transport a

physically handicapped person or persons when the modified vehicle is sold to a physically handicapped person, as defined.

(d) Repairs to Modified Vehicles. Tax does not apply to the sale or use of items and materials used to repair the modified portion (the portion that contains equipment previously used to modify the vehicle) of a vehicle used to transport a physically handicapped person or persons. Once installed, such "repair parts" qualify as items and materials used to modify a vehicle in order for the vehicle to be used to transport a physically handicapped person or persons.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.4, Revenue and Taxation Code.

REGULATION 1591.4. MEDICAL OXYGEN DELIVERY SYSTEMS.

(a) Definitions.

(1) Physician. "Physicians" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(2) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

[1.] The name or names and address of the patient or patients.

[2.] The name and quantity of the drug or device prescribed and the directions for use.

[3.] The date of issue.

[4.] Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

[5.] A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

[6.] If in writing, signed by the prescriber issuing the order.

(3) Health Facility. "Health Facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(4) Medical Oxygen Delivery System. A system used to administer oxygen directly into the lungs of the patient for the relief of conditions in which the human body experiences an abnormal deficiency or inadequate supply of oxygen. Devices that only assist the patient in breathing, but do not deliver air or oxygen directly into the lungs of the patient, do not qualify as medical oxygen delivery systems.

(b) Tax Application.

(1) Medical Oxygen Delivery Systems. Tax does not apply to the sale or use of medical oxygen delivery systems when sold, leased or rented to an individual for the personal use of that individual as directed by a licensed physician. Medical oxygen delivery systems include, but are not limited to, liquid oxygen containers, high-pressure cylinders, regulators, oxygen concentrators, tubes, masks and related items necessary for the delivery of oxygen to the patient. The term also includes repair and replacement parts for use in such a system.

(2) Ventilators and Other Respiratory Equipment. For the purposes of this regulation, ventilators that produce a form of controlled respiration in which compressed air is delivered under positive pressure into the patient's airways qualify for the exemption provided under Section 6369.5 for medical oxygen delivery systems. Pressure ventilators and volume ventilators provide assisted respiration and intensive positive pressure in which compressed air, a component of which is oxygen, is administered into the breathing systems of patients to help them breathe. The sale or use of ventilators, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician

Respiratory equipment that induces air into the lungs of a patient, through the application of pressure to the chest area, also qualifies for the exemption provided for medical oxygen delivery systems, regardless of whether the pressure applied is negative pressure or positive pressure. The sale or use of respiratory equipment, as described, is exempt from tax when sold or leased to an individual for the personal use of that individual as directed by a physician. Included within the scope of the exemption are exsufflation belts, iron lungs, chest shells, pulmo wraps, and the pumps and regulators necessary for the operation of the listed equipment.

(c) Sales to Health Facilities and Health Care Providers. Sales of medical oxygen delivery systems are exempt when sold to an individual for his or her own use under the direction of a licensed physician. Sales of medical oxygen delivery systems to hospitals, immediate care facilities, physicians, or other health care providers for use on their premises are subject to tax in the same manner as other sales of tangible personal property.

A rental or lease of a medical oxygen delivery system to a health facility qualifies for an exemption from tax when the facility intends to lease or rent the system to an individual for the personal use of that individual as directed by a licensed physician and the system is then leased or rented as intended. However, the transaction between the health facility and the individual must constitute an actual lease or rental. When the patient's use of the medical delivery system is limited to the health facility's premises, the direction and control of the equipment does not transfer to the patient. Therefore, an actual lease or rental of the system to the patient does not occur even when a separate billing is made to the patient for the use of the system. As such, the lease or rental of the system to the health facility does not qualify for the exemption provided under Section 6369.5.

(d) Sales of Medical Oxygen. Medical oxygen and other gases sold to a licensed physician and surgeon, podiatrist, dentist, or health facility for treatment of human beings are considered medicines. Therefore, their sale or use is not subject to tax when (1) furnished by a licensed physician and surgeon, podiatrist, or dentist to his or her own patient or (2) furnished by the health facility pursuant to the order of a licensed physician and surgeon, dentist, or podiatrist.

Medical oxygen sold by distributors of compressed gases to an individual for use as part of the individual's treatment, pursuant to a physician's prescription, is regarded as a medicine furnished by a licensed physician to his or her own patient for treatment of the patient as provided by Regulation 1591(b)(2). Sales of medical oxygen to individuals under the "Casey Bill" (i.e., the

retailer bills the service acting as a fiscal agent for the State of California) are regarded as sales of medicines to this State for use in the treatment of human beings as provided by Regulation 1591(b)(5). Therefore, sales of medical oxygen by such distributors, under these conditions, are not subject to tax whether or not the distributor is a medical supply house.

(e) Sales to Insured Persons. The exemption for qualifying retail sales of oxygen delivery systems and replacement parts is not affected by the fact that charges to the individual for whom such items are sold, leased, or rented may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

NOTE: Authority: Section 7051, Revenue and Taxation Code.

Reference: Sections 6006, 6369, and 6369.5, Revenue and Taxation Code.